

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Fay et al.)	Examiner:
)	Marsha M. Tsay
Serial No.	:	10/581,471)	
)	Art Unit:
Cnfrm. No.	:	3888)	1656
)	
Filed	:	December 2, 2004)	
)	
For	:	RECOMBINANT FACTOR VIII HAVING)	
		INCREASED SPECIFIC ACTIVITY)	
)	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This submission is in response to the January 7, 2008, office action, imposing a written restriction requirement. This response is being filed with a Petition for a Two Month Extension of Time.

In response to the restriction requirement, applicants hereby elect Group I (i.e., claims 1-6, 9, 11, 12, and 48-52) with traverse.

Applicants traverse this restriction on the basis that unity of invention does exist. The U.S. Patent and Trademark Office ("PTO") asserted on page 2 of the office action that unity is lacking based on U.S. Patent No. 5,859,204 to Lollar et al. ("Lollar"), citing Table 1 as identifying several domains to be mutated. Applicants respectfully disagree. Lollar is primarily concerned with chimeric (mutant) forms of factor VIII that have reduced reactivity to inhibitory antibodies while retaining procoagulant activity, and the regions identified in Table I of Lollar are identified for that purpose. In contrast, the claimed recombinant factor VIII (of Group I) includes a point mutation in or near at least one calcium binding site of a wild-type factor VIII, where the resulting recombinant factor VIII has

- 2 -

increased specific activity relative to wild-type factor VIII. The PTO has failed to demonstrate where Lollar teaches these limitations of the invention; Lollar, therefore, cannot destroy unity in this invention.

Moreover, the nucleic acid molecule of Group II, and its use, includes all limitations of the product of Group I. For this reason, unity exists in the present application, and all claims of Groups I and II should be examiner together.

If any further action is required by the applicants, then the applicants invite the examiner to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: April 7, 2008

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

Nixon Peabody LLP
1100 Clinton Square
Rochester, New York 14604
Telephone: (585) 263-1128
Facsimile: (585) 263-1600